

ALBA BOTANICA KIDS MINERAL SUNSCREEN FF SPF30- zinc oxide, titanium dioxide cream

The Hain Celestial Group, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Alba Botanica Kids Mineral Sunscreen Lotion SPF 30

Titanium Dioxide 2.0%

Zinc Oxide 14.5%

Helps prevent sunburns. If used as directed with other sun protection measures decreases the risk of skin cancer and skin aging caused by the sun. **Sun Protection Measures:** Spending time on the sun increases your risk of skin cancer and skin aging. To decrease the risk regularly use Broad Spectrum Sunscreen with SPF 15 or higher and other protective measures including: limit time in sun, especially from 10am to 2 pm, and wear long-sleeved shirts, pants, hats and sunglasses.

For external use only. Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if skin rash occurs.

Sunscreen

Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

Water, Caprylic/Capric Triglyceride, Dimethicone, Ethylhexyl Palmitate, Sorbitan Sesquioleate, Glycerin, Glyceryl Isostearate, Butyrospermum PARKII (Shea Butter), Polyglyceryl-3 Ricinoleate, Helianthus Annuus (Sunflower) Seed Oil (1), Simmondsia Chinensis (Jojoba) Seed Oil (1), Vitis Vinifera(Grape) Seed Oil, Aloe Barbadensis Leaf Juice (1), Calendula Officinalis Flower Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Tocopheryl Acetate, Alcohol, Magnesium Sulfate, Polyhydroxystearic Acid, Silica, Sodium Chloride, Benzyl Alcohol, Phenoxyethanol.



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zinc oxide, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2088
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14.5 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	

GLYCERIN (UNII: PDC6A3C00X)
DIMETHICONE (UNII: 92RU3N3Y1O)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SHEA BUTTER (UNII: K49155WL9Y)
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALCOHOL (UNII: 3K9958V90M)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
WATER (UNII: 059QF0KO0R)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ALOE (UNII: V5VD430YW9)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
CHAMOMILE (UNII: FGL3685T2X)
SUNFLOWER OIL (UNII: 3W1JG795YI)
GRAPE SEED OIL (UNII: 930MLC8XGG)
BENZYL ALCOHOL (UNII: LKG8494WBH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2088-4	113 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2017	

Labeler - The Hain Celestial Group, Inc. (117115556)

Registrant - The Hain Celestial Group, Inc. (081512382)

Establishment

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		081512382	manufacture(61995-2088)